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The goals of this project are to develop a computerized decision analysis model concerning the risks and benefits of hormone replacement therapy for breast cancer survivors.

During the first year, we updated our literature search and review and found numerous studies relevant to our question. We developed a pilot instrument to measure patient preferences, but found that this did not provide useful information. We began construction of two alternative decision analysis models. During the second year we continued development of the models. Because of the complexities of developing valid instruments for measuring patient preferences (utilities), we rearranged our budget to permit us to obtain the consultative services of Dr. Albert Wu of John Hopkins University, an authority on measurement of quality of life, and colleagues.

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# INTRODUCTION

The benefits and risks of hormone replacement therapy (HRT) for post-menopausal women have been studied extensively, and yet for most women the choice remains one of uncertainty. HRT is widely believed to decrease the future risk of coronary heart disease, osteoporosis, and stroke, but also it is widely believed to increase the future risk of breast and endometrial cancer. The addition of progestin to estrogen is believed to eliminate the increased risk of endometrial cancer, but may also lessen the preventive effect on coronary heart disease risk. HRT is also known to affect serum lipoproteins, sexual function, and urinary function, and it can cause endometrial hyperplasia and other adverse effects, and may require invasive monitoring procedures. Although the American College of Physicians and others have studied HRT and provide guidelines for women with a variety of risk factors, none of the recommendations apply to women with a history of breast cancer. In addition, the guidelines apply to population groups and not to individuals. Any individual may value a health state, an intervention, or the future risk of an illness differently than do others. Personal decisions regarding preventive medicine therefore should reflect these valuations.

It is widely believed that HRT is contraindicated in postmenopausal women who have had breast cancer. However, HRT has not been adequately studied among breast cancer survivors. The detection of early breast cancer has increased dramatically during the last decade accompanied with a rise in five year survival of treated patients, so there are many women who need guidance. There are approximately 182,000 new cases of breast cancer in women in the U.S. per year. Since the majority of these women will have localized disease can expect to survive 20 years or more, they will face risks of vascular and bone disease similar to those without a history of breast cancer. The induction of premature menopause with adjuvant chemotherapy increases the risk of coronary artery disease and osteoporosis among these women. The prohibition of HRT may diminish overall survival and quality of life among breast cancer survivors despite higher risk of endometrial and breast carcinoma with this intervention

Until the results of clinical trials of HRT in breast cancer survivors are available, which will take many years, it will remain uncertain as to whether this population of women should be given HRT. While we await such results, we are developing a decision analysis method utilizing a mathematical model to provide guidance for women with breast cancer as to whether they should take HRT.

## BODY

The goals of this project are to develop a computerized decision analysis model concerning the risks and benefits of hormone replacement therapy for breast cancer survivors.

During the first year, we updated our literature search and review and found numerous studies relevant to our question. We developed a pilot instrument to measure patient preferences, but found that this did not provide useful information. We have begun construction of two alternative decision analysis models. During the next year we plan to continue development of the model. Because of the complexities of developing valid instruments for measuring patient preferences (utilities), we have rearranged our budget to permit us to obtain the consultative services of Dr. Albert Wu of John Hopkins University, an authority on measurement of quality of life.

**Results to date:**

As of October 29, after 6 weeks of recruitment at the Johns Hopkins site we have the following:

Total calls attempted: 122

| | | |
|---|---|---|
| # Unreachable | 37 | (Most not at home when called) |
| # No's | 46 | (Most not interested or won't have time) |
| # Ineligible | 11 | (Mostly not peri-post menopausal) |
| # Yes's | 40 | |
| # Interviews | 28 | (The rest did not show, or were ineligible) |

21 interviews have been in the General Internal Medicine Clinic, and 7 in the Breast Cancer Clinic. For now we will continue recruiting as we have been, but are considering ways to increase recruitment in the breast center. For instance, we are thinking about loosening the eligibility criteria to include women up to 5 years after their last treatment for breast cancer (instead of the current 3 years).

## CONCLUSIONS

At this early stage in the project, we have not reached any conclusions.

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